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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,435	01/22/2004	Pablo Umana	1975.0180003/TJS	3728

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EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
01/25/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,435	UMANA ET AL.	
	Examiner	Art Unit	
	Michael Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-34, 65-68, 74, 82-95, 186, 188-190, 206-212 and 287 - 307* is/are pending in the application.

4a) Of the above claim(s) *287-307* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-34,65-68,74,82-95,186,188-190 and 206-212* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/10;1/6/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt and entry of the amendment dated 10/22/2010 is acknowledged. After entry of the amendment, claims 30-34, 65-68, 74, 82-95, 186, 188-190, 206-212 and 287 - 307 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

Newly submitted claims 287 - 307 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they recite a non-elected Group (hereinafter Group VII) as set forth in the restriction requirement dated 12/14/2006, i.e. they are directed to the non-elected element (β(1,4)-galactosyltransferase activity) of the linking claim requirement as set forth on page 4 of the restriction requirement dated 12/14/2006. Applicants elected β(1,4)-N-acetylglucosaminyltransferase activity within said linking claim analysis in the reply dated 2/14/2007. As amended, the pending claims no longer comprise a generic claim reciting both species of enzyme activities found, for example, in claim 30 as originally filed.

Accordingly, claims 287 - 307 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

Claims 30-34, 65-68, 74, 82-95, 186, 188-190, and 206-212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umana et al (WO 99/54342,) Grabenhorst et al (1999, JBC) and Shields et al (JBC, 2002, of record) in view of Russell et al (WO 01/29242 A2, 2001) and Rabouille et al (1995, J. Cell Sci., cited by applicants). **This rejection is maintained for reasons made of record in the Office Action dated 1/21/2010, and for reasons set forth below.**

The claims have been amended to remove a limitation, or to introduce limitations found in canceled claims (e.g. claim 73) included in this rejection in prior Office Actions, and thus previously addressed.

Response to Arguments

Applicant's arguments filed 7/21/2010 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) the teachings of Umana et al are clearly speculative, and thus are an invitation to experiment; 2) Umana et al teach away from redistributing GalT towards the trans-Golgi cisterna, which includes the medial Golgi; 3) Grabenhorst et al do not teach moving GalT or GnTIII to the trans Golgi and thus does not cure the deficiencies of Umana et al, Grabenhorst et al does not provide any teaching or suggestion to modify GalT or GnTIII by adding the localization domain of ManII, and there is no reasonable expectation of success when combining Umana and Grabenhorst et al; 4) Shields et al do not teach the redistribution of GalT or GnTIII and thus does not cure the deficiencies of Umana et al, and there is no reasonable expectation of success when combining Umana, Grabenhorst and Shields et al; 5) Russell and Rabouille et al do not cure the deficiencies of Umana et al, and there

is no reasonable expectation of success when combining Umana, Grabenhorst, Russell, and Shields et al; 6) unexpected superior results rebut this obviousness rejection

Regarding 1), this assertion is false on its face. Umana et al propose known solutions to the problem, i.e. exchanging the localization domain of GalT with that of a Golgi enzyme having the desired locale in the Golgi apparatus, in the very next sentence after that quoted by applicants. This assertion thus ignores the remainder of the prior art cited in this rejection and by Umana et al, teaching the routine exchange of such domains and the predictable redistribution of the modified enzymes.

Regarding 2), the reasoning behind this assertion is less than clear. First, it is not established that the medial Golgi includes the trans Golgi, as applicants insist. The evidence at hand indicates that they are distinct compartments, perhaps with some overlap. Second, and more important, the basis for this rejection has never been redistribution of GalT to the trans Golgi. Rather, redistribution of GnTIII to the medial Golgi is the crux of this rejection.

Regarding 3), again, the basis for this rejection has never been redistribution of GalT or GnTIII to the trans Golgi. Applicants assertions are thus less than convincing. Grabenhorst et al do teach the localization of FT-6 to the medial Golgi, which is the point of the rejection.

Regarding 1) - 5), applicants unsupported assertions that there is no reasonable expectation of success when combining the references are less than convincing in light of the reasoning provided by the Examiner and the extensive teachings provided by the prior art of record. "Argument of counsel cannot take the place of evidence lacking in the record." In re Scarbrough, 182 USPQ 298, 302 (CCPA 1974).

Further regarding 1) - 5), in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding 6), applicants fail to point out what exactly is unexpected and superior in the results of Ferrara et al relative to the teachings of the prior art. Given the evidence available, one of skill in the art would expect a change in glycosylation profile of proteins prepared from cells expressing the claimed fusion proteins relative to control cells having no such modification. Umana et al teach or suggest all that is found in Ferrara et al, that is, the modification of the glycosylation profile of antibodies for increased ADCC via redistribution of the desired glycosyltransferases. Umana et al suggest one way of doing so is to modify the distribution of GalT such that it found after GnTIII in the glycosylation pathway. Moving GnTIII to a point before GalT in said pathway is a simple and obvious alternative, for reasons of record, to moving GalT. One of skill in the art would expect after such redistribution not only a change in the glycosylation profile, but a profile that according to Umana et al would increase ADCC. Finally, such secondary considerations such as unexpected results, even if accepted as truly unexpected, do not automatically outweigh a finding of obviousness.

Double Patenting

Applicant is advised that should claim 65 be found allowable, claims 66 and 67 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 66 and 67 recite limitations already found in claim 65, albeit in slightly different wording. A GnTIII catalytic domain (claim 66) is necessary for GnTIII activity as recited in claim 65, and the localization domain recited in claim 67 is already recited in claim 65.

Applicant is advised that should claim 186 be found allowable, claims 188 and 189 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 188 and 189 recite limitations already found in claim 186, albeit in slightly different wording. A GnTIII catalytic domain (claim 188) is necessary for GnTIII activity as recited in claim 186, and the localization domain recited in claim 189 is already recited in claim 186.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633